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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. Ackrad-5
First Inventor or Application Identifier Ackerman
Title SINGLE LUMEN CATHETER APPARATUS
Express Mail Label No. EJ596854863US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Specification [Total Pages 13]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets 2]
4. Oath or Declaration [Total Pages 15]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
 - i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

* NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

5. ☐ Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. ☒ Assignment Papers (cover sheet & document(s))
8. ☐ 37 C.F.R. § 3.73(b) Statement of Power of Attorney
(when there is an assignee)
9. ☐ English Translation Document (if applicable)
10. ☐ Information Disclosure Statement (IDS)/PTO-1449 [Copies of IDS Citations]
11. ☐ Preliminary Amendment
12. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. ☒ * Small Entity Statement(s) filed in prior application, Status still proper and desired
(PTO/SB/09-12)
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☐ Other:

16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: _____
Prior application information: Examiner _____ Group / Art Unit: _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

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or ☒ Correspondence address below

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Signature	<i>Paul A. Schwarz</i>	Date	11/24/99

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**STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN**

Docket Number (Optional)
Ackrad-5

Applicant, Patentee, or Identifier: Bernard Ackerman
Application or Patent No.: Herewith
Filed or Issued: Herewith
Title: SINGLE LUMEN BALLOON CATHETER APPARATUS

I hereby state that I am

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN Ackrad Laboratories, Inc.

ADDRESS OF SMALL BUSINESS CONCERN 70 Jackson Drive, Cranford, NJ 07106

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

- ☒ the specification filed herewith with title as listed above.
☐ the application identified above.
☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

- Each person, concern, or organization having any rights in the invention is listed below:
☐ no such person, concern, or organization exists.
☐ each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Bernard Ackerman

TITLE OF PERSON IF OTHER THAN OWNER President

ADDRESS OF PERSON SIGNING 70 Jackson Drive, Cranford, NJ 07106

SIGNATURE Bernard Ackerman DATE Nov. 19, 1999

"EXPRESS MAIL CERTIFICATE"

"Express Mail" mailing label number: EJ596854863US

Date of Deposit: November 24, 1999

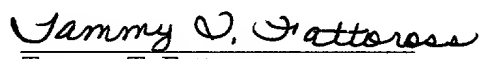
Title of Invention: SINGLE LUMEN BALLOON CATHETER APPARATUS

Inventor: ACKERMAN, Bernard

Type of Documents:

1. Utility Patent Application Transmittal;
2. Fee Transmittal;
3. Application consisting of 7 pages of specification, 5 pages of claims, 1 page of Abstract and 2 pages of drawings;
4. One Verified Small Entity Statement;
5. Declaration and Power of Attorney (executed);
6. One Assignment;
7. Assignment Recordation Form;
8. PTO - Form 1449;
9. IDS References;
9. Our checks in the amount of \$389.00 and \$40.00;
10. Acknowledgment Postcard; and,
11. "Express Mail" Certificate.

I hereby certify that this paper and fee are being deposited with the United States Postal Service's "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to Assistant Commissioner for Patents, "Box Application," Washington, D.C. 20231.


Tammy T. Fattoross

SINGLE LUMEN BALLOON CATHETER APPARATUS

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FIELD OF THE INVENTION

The present invention relates to catheters, and in particular, to a balloon-bearing single lumen catheter for injecting diagnostic fluids into a body cavity and a catheter apparatus employing same.

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BACKGROUND OF THE INVENTION

Diagnostic procedures which require a non-surgical entry into the uterus are well known. One such procedure known as hysterosalpingography, is a radiographic method for imaging the anatomical structures of the uterus and fallopian tubes. Hysterosalpingography involves inserting a fine flexible catheter through the cervical canal and injecting a contrast medium, such as an iodinated fluid, into the uterus. Radiography is then carried out to provide imaging information pertaining to the subject uterus.

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Another well known diagnostic procedure which entails the non-surgical entry into the uterus is called hysterosonography. This procedure also employs a fine flexible catheter that is inserted into the cervical canal of the uterus. The catheter in this procedure enables the physician or technician to inject a sterile saline solution into the uterus to expand it so that an ultrasound scanner can be used to sonographically observe the uterus.

The catheters used in both procedures typically have means for sealing off the uterus after injection of the fluid to prevent backflow into the vaginal canal. One such means includes an

inflatable intrauterine balloon made from an elastomeric material disposed adjacent the distal tip of the catheter. The catheter includes a first lumen that communicates with the interior of the balloon to enable inflation and deflation with an inflation syringe, and second lumen that is open at the distal tip of the catheter to enable injection of a desired diagnostic fluid into the uterus with a injection syringe.

The balloon catheter is operated by inserting the distal tip thereof through the cervical canal and into the uterus with the intrauterine balloon deflated. The insertion of the distal tip operates to position the deflated intrauterine balloon in the uterus or cervical canal. Once positioned, the inflation syringe is used to inflate the intrauterine balloon with air to seal block the cervical canal and the injection syringe is used to inject the desired diagnostic fluid into the uterus.

One problem associated with balloon catheters of this design is that they are relatively expensive to manufacture because they include two lumens and double syringes. Therefore, a less expensive balloon-bearing catheter is needed.

SUMMARY OF THE INVENTION

A catheter used for non-surgically entry into a uterus to dispense a diagnostic fluid therein; the catheter comprising a tubular body having a lumen extending from a first end thereof to a second end thereof. The lumen includes an external opening adjacent the first end for dispensing a diagnostic fluid into the interior of a subject uterus, and a balloon disposed marginally adjacent to the first end of the body for fluid sealing the interior of the subject uterus. The lumen further includes a second opening in fluid communication with the interior of the balloon for inflation thereof with the diagnostic fluid.

The catheter is typically combined with a syringe to form a catheter apparatus if desired.

BRIEF DESCRIPTION OF THE DRAWINGS

5 The advantages, nature, and various additional features of the invention will appear more fully upon consideration of the illustrative embodiments now to be described in detail in connection with accompanying drawings wherein:

FIG. 1 is an elevational view of a catheter apparatus according to an embodiment of the invention;

FIG. 2 is a sectional view of the catheter of the apparatus;

FIG. 3A is a diagrammatic view of the catheter of the invention anchored in the cervical canal of a subject uterus;

FIG. 3B is a diagrammatic view of the catheter of the invention anchored in the uterine cavity of a subject uterus; and

FIG. 4 is an enlarged diagrammatic view of the distal portion of the catheter of the invention.

It should be understood that the drawings are for purposes of illustrating the concepts of the invention and are not necessarily to scale.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a catheter apparatus according to an embodiment of the invention. The catheter apparatus 10 is an inline assembly comprised of a flexible, single lumen catheter 11 and a

conventional syringe 12. The catheter apparatus 10 is primarily intended for non-surgical entry into the uterine cavity, however, one of ordinary skill in the art will recognize its usefulness in other related procedures.

The catheter 11 of the apparatus 10 includes a flexible tubular body 16 which is preferably made from a clear polyurethane or like material. The body 16 has a distal end 17 and proximal end 18 and is threadedly disposed in a semi-rigid sheath 13 which is preferably made from polypropylene or any other suitable material. The sheath 13 has a distal end 24, a proximal end 25, and a length which is about 40% percent less than the length of the catheter body 16. The sheath 13 can be slidably moved back and forth along the catheter body 16 to uncover the distal portion of the body 16 to allow it to bend and flex freely or to cover it to prevent bending and flexing in the vagina thus aiding the insertion of the catheter 11 in the cervical canal. A conventional female Luer hub connector 14 is provided at the proximal end 18 of the catheter body 16 for detachably fluid coupling the syringe 12 (which should be equipped with a male Luer connector) to the catheter 11. An inflatable balloon 20 (shown in the deflated state) is affixed to and encloses a marginal distal end portion of the body 16. The balloon 20 can be of the type described in U.S. Patent 5,624,399 issued to Bernard Ackerman the disclosure of which is incorporated herein by reference.

The balloon 20 taught in Patent 5,624,399 is typically constructed from an elastomeric material such as polyurethane or any other elastomeric material having a Shure A durometer of between approximately 70 and 95. Patent 5,624,399 further teaches attaching the balloon 20 to the body 16 so that its longitudinal axis L is longer than its transverse axis T upon initial inflation thereof. This allows the balloon 20 to be progressively transformed from an ellipsoidal shape to a spherical shape with increasing inflation pressure. The balloon 20 in the ellipsoidal shape as

shown in FIG. 3A, can be used for occluding the cervical canal 32 of a subject uterus 31 thus preventing obstruction of the uterus 31 during imaging. If pain and/or cramping is experienced with the balloon 20 in the cervical canal 32, it can be moved into the uterine cavity 33 of the subject uterus 31 and further expanded into the spherical shape to block the internal opening 34 of the cervical canal 32 as shown in FIG. 3B to obviate the pain and/or cramping.

It should be understood that other embodiments of the invention can employ more conventional balloon designs. Such balloon designs typically inflate into a spherical shape and are made from latex.

FIG. 2 shows a cross-sectional view through the catheter 11 of the apparatus 10. As can be seen, the body 16 of the catheter 11 is constructed with a single lumen 21 that extends virtually the entire length thereof. The wall 19 of the lumen 21 includes a first slit 22 (best shown in FIG. 4) adjacent to the distal end 17 of the body 16. The first slit 22 allows the lumen 21 to communicate with the external environment to provide a fluid communication path for injecting a diagnostic fluid such as saline or a contrast dye into a the uterine cavity of a subject uterus. The lumen 21 also communicates with the interior of balloon 20 via a second slit 23 (best shown in FIG. 4) provided in the wall 19 of the lumen 21. The second slit 23 is equal to or up to 28 percent larger in area than the first slit 22 to provide a communication path for inflating the balloon 20 with diagnostic fluid as will be explained further on. In other embodiments of the invention, either one or both of the slits 22, 23 can be replaced with a correspondingly placed aperture(s).

The apparatus 10 is typically operated by moving the sheath 13 toward the distal end 17 of the catheter 11, to cover the most of the distal portion of the catheter body 16 (the balloon 20 should be deflated). The catheter 11 is then inserted into the vaginal canal so that the distal end

17 of the catheter 11 just enters the cervical canal of a subject uterus and the distal end 24 of the sheath 13 abuts against the end of the cervix. The catheter 11 is then threaded through the sheath 13 to position the balloon 20 in the cervical canal, or just past the cervical canal inside the uterine cavity of the uterus (FIG. 3A).

5 The syringe 12 of the apparatus 10, which is filled with a diagnostic fluid such as saline or a contrast dye, is then operated to inject the diagnostic fluid into the uterine cavity of the uterus. The fluid pressure generated within the lumen 21 by the operation of the syringe 12 causes the first slit 22 at the distal end 17 of the catheter body 16 to open and allow the diagnostic fluid to flow from the catheter 11 into the uterine cavity of the uterus. At the same time as the uterus is being filled with the fluid, back-pressure within the lumen 21 of the catheter 11 caused by restricted fluid flow through the first slit 22 causes the second slit 23 to open to allow fluid to enter and inflate the balloon 20, thus preventing leakage of fluid through the cervical canal.

15 Once the balloon 20 is inflated, the slits 22, 23 operate as check valves by automatically closing to prevent the balloon 20 from deflating. The inflated balloon 20 locks the position of the apparatus 10 and seals the uterine cavity to prevent leakage of the diagnostic fluid therefrom. Radiography or sonography can then be performed to provide imaging information pertaining to the subject uterus or fallopian tubes.

20 When it is desirable to deflate the balloon 20, the syringe 12 is uncoupled from the catheter 11 and the catheter is withdrawn slightly through the cervix. This causes the muscular tissue of the cervix to compress the balloon 20 slightly thus forcing the fluid in the balloon back into the lumen

21 of the catheter 11 through the slit 23. Once the balloon 20 is deflated, the catheter 11 of the apparatus 10 can be fully withdrawn from the uterus through the cervical canal.

While the foregoing invention has been described with reference to the above embodiments, various modifications and changes can be made without departing from the spirit of the invention. Accordingly, all such modifications and changes are considered to be within the scope of the appended claims.

CLAIMS

What is claimed is:

1. A catheter useful for non-surgical entry into a uterus to dispense a diagnostic fluid therein, the catheter comprising:

a tubular body having a lumen extending from a first end thereof to a second end thereof, the lumen having an external opening adjacent the first end for dispensing a diagnostic fluid into the interior of a subject uterus; and

a balloon disposed marginally adjacent to the first end of the body for fluid sealing the interior of the subject uterus;

the lumen having a second opening in fluid communication with the interior of the balloon for inflation thereof with the diagnostic fluid.

2. The catheter according to claim 1, wherein the body is flexible.

3. The catheter according to claim 2, further comprising a movable sheath that can be moved to a first position to cover a portion of the body to add rigidity thereto thus aiding in the insertion of the catheter, and which can be moved to a second position to uncover the portion of the body thus allowing it to bend and flex freely.

4. The catheter according to claim 1, wherein the balloon can be sequentially inflated into first and second predetermined shapes.

10. The catheter apparatus according to claim 9, wherein the second opening prevents fluid back-flow in the lumen to maintain inflation of the balloon.

11. The catheter apparatus according to claim 9, wherein the catheter is flexible.

12. The catheter apparatus according to claim 11, further comprising a movable sheath that can be moved to a first position to cover a portion of the body to add rigidity thereto thus aiding in the insertion of the catheter, and which can be moved to a second position to uncover the portion of the body thus allowing it to bend and flex freely.

13. The catheter apparatus according to claim 9, wherein the balloon can be sequentially inflated into first and second predetermined shapes.

14. The catheter apparatus according to claim 13, wherein the first predetermined shape is substantially elliptical and the second predetermined shape is substantially spherical.

15. The catheter apparatus according to claim 13, wherein the balloon is made from polyurethane.

16. The catheter apparatus according to claim 9, wherein the balloon is made from polyurethane.

17. A method for making a catheter which is useful for non-surgical entry into a uterus to dispense a diagnostic fluid therein, the method comprising the steps of:

providing a tubular body having a lumen extending from a first end thereof to a second end thereof,

creating an external opening adjacent the first end of the body, the external opening for dispensing a diagnostic fluid into the interior of a subject uterus;

attaching a balloon marginally adjacent to the first end of the body, the balloon for fluid sealing the interior of the subject uterus; and

creating a second opening in the lumen which is in fluid communication with the interior of the balloon for inflation thereof with the diagnostic fluid.

18. The method according to claim 17, further comprising the step of providing a syringe that delivers the diagnostic fluid into the catheter, the syringe and the catheter forming a catheter apparatus.

19. The method according to claim 17, wherein the second opening prevents fluid back-flow in the lumen to maintain inflation of the balloon.

20. The method according to claim 17, wherein the catheter is flexible.

21. The method according to claim 20, further comprising the step of providing a movable sheath that can be moved to a first position to cover a portion of the body to add rigidity

thereto thus aiding in the insertion of the catheter, and which can be moved to a second position to uncover the portion of the body thus allowing it to bend and flex freely.

ABSTRACT

A catheter useful for non-surgical entry into a uterus to dispense a diagnostic fluid therein. The catheter includes a tubular body having a lumen extending from a first end thereof to a second end thereof. The lumen includes an external opening adjacent the first end for dispensing a diagnostic fluid into the interior of a subject uterus, and a balloon disposed marginally adjacent to the first end of the body for fluid sealing the interior of the subject uterus. The lumen further includes a second opening in fluid communication with the interior of the balloon for inflation thereof with the diagnostic fluid. In most applications, the catheter can be combined with a syringe to form a catheter apparatus.

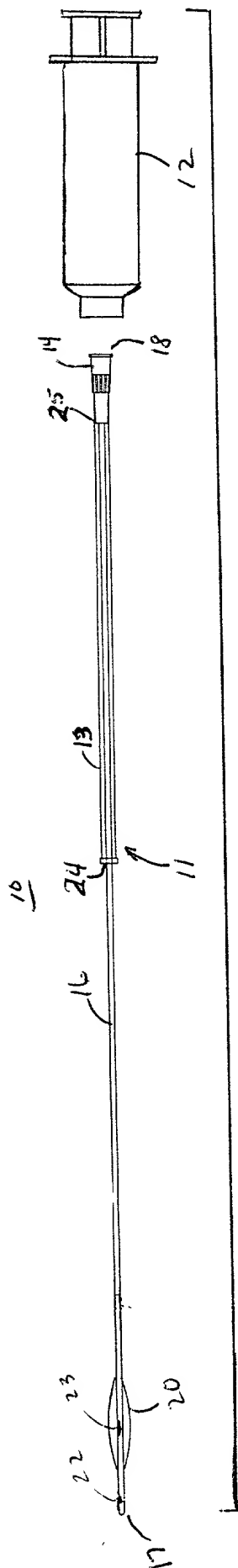


Fig. 1

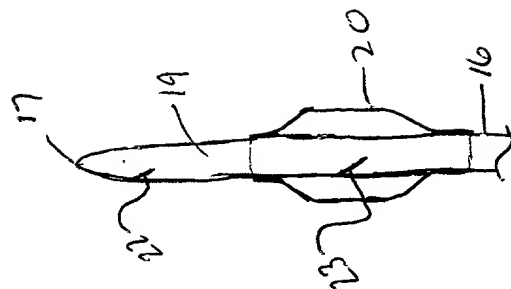


Fig. 4

Embodiment

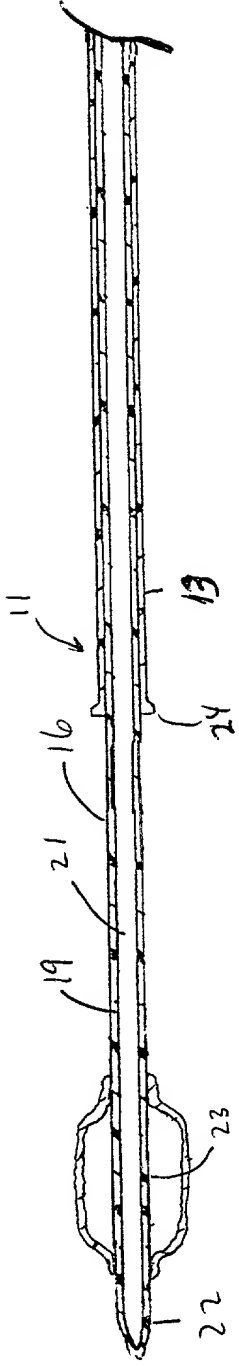


Fig. 2

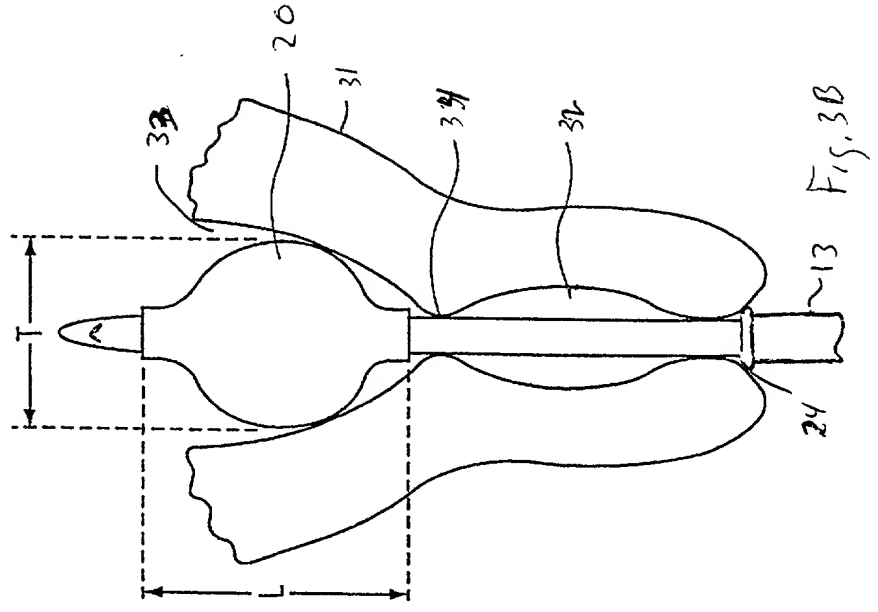


Fig. 3A

Fig. 3B

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Attorney Docket Number	Ackrad-5
	First Named Inventor	Ackerman
	COMPLETE IF KNOWN	
	Application Number	/ Herewith
	Filing Date	Herewith
	Group Art Unit	TBA
	Examiner Name	TBA

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SINGLE LUMEN BALLOON CATHETER APPARATUS

the specification of which (Title of the Invention)
☒ is attached hereto
OR
☐ was filed on (MM/DD/YYYY) [] as United States Application Number or PCT International Application Number [] and was amended on (MM/DD/YYYY) [] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

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OR

☒ Registered practitioner(s) name/registration number listed below

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Name	Registration Number	Name	Registration Number
Arthur L. Plevy	24,277	Jonathan M. Darcy	44,054
Edward J. Howard	42,670	Paul A. Schwarz	37,577

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label

OR ☒ Correspondence address below

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Address					
City	Princeton	State	NJ	ZIP	08540
Country	US	Telephone	(609) 987-6883	Fax	(609) 520-0360

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))		Family Name or Surname					
Bernard		Ackerman					
Inventor's Signature	<i>Bernard Ackerman</i>		Date	11/19/99			
Residence: City	Metuchen	State	NJ	Country	US	Citizenship	US
Post Office Address	17 Sterling Court						
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☐ Additional inventors are being named on the supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto